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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,509	01/25/2001	Fumiaki Katagiri	NADIL018A	5860

22847 7590 12/24/2003

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EXAMINER

VOGEL, NANCY T

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/770,509

Applicant(s)

KATAGIRI, FUMIAKI

Examiner

Nancy. Vogel

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/14/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,9,10,12,13,20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,9 and 10 is/are allowed.
- 6) ☒ Claim(s) 12,13,20 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

This action is in response to applicant's amendment filed 10/14/03. Claims 1, 2, 9, 10, 12, 13, 20 and 21 are pending in the case.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, and by dependence claims 13, 17, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons made of record set forth in Paper No. 20, mailed 6/30/03, at pages 7-8.

Applicants have argued in their response mailed 10/14/03, that the specification as filed and antimicrobial assays are known to those in the art to determine if an inhibitor of FtsZ-mt would have antimicrobial activity (page 5 of the response). While this is agreed with, it is noted that the claims are directed to a method of identifying an inhibitor of FtsZ-mt activity having antimicrobial activity, and no assay or guidance has been

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provided regarding how to identify an inhibitor of oomycete FtsZ-mt activity. Applicants further argue that "[o]ne skilled in the art would know to test if a compound is an inhibitor if it prevents or retards the formation of the "ring" and cell division in oomycetes" (page 5 of the response). However, this information is not set forth in the specification, and it is maintained that the actual activity of the FtsZ-mt is unknown, making identification of inhibitors of its activity problematic. The specification at page 3 states that "The bacterial cell division protein Ftsz is a key component of the bacterial cell division machinery. Fusion constructs of Ftsz with green-fluorescent protein have shown that, at the onset of division, Ftsz forms a filamentous ring at the site of cell division, and disassembles after septation is complete. FtsZ can self-assemble into rafts of long filaments having curving edges, as well as into sheets and rings. A cytoskeletal role for Ftsz has been postulated based on its ability to undergo GTP-dependent polymerization in vitro and its similarity to tubulin." None of this information provides a definitive activity of FtsZ-mt, or a method for identifying an inhibitor of said activity. Therefore, it is maintained that the written description requirement has not been satisfied.

Claims 12, and by dependence, claims 13, 17, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained for reasons made of record set forth in Paper No. 20, mailed 6/30/03, at pages 8-9.

Applicants have argued in their response mailed 10/14/03, that the amendments to the claims to more particularly recite the use of SEQ ID NO:2 for use in the claimed methods, and that it would not require undue experimentation to use a described protein in a screening method (page 5 of the response). However, the amendments to the claims have not remedied the lack of guidance in the specification regarding how to practice the invention which requires the identification of inhibitors of the FtsZ activity. For the reasons made of record, it would require undue experimentation to determine methods of identifying said inhibitors. Therefore the rejection is maintained.

Claims 1, 2, 9, 10 are allowed.

#### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel whose telephone number is (703) 308-4548. The examiner can normally be reached on 7:30 - 4:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196. As of January 13, 2004, the examiner's phone number will be (571) 272-0780.

ntv



JAMES KETTER  
PRIMARY EXAMINER